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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,555	12/08/2003	Katerina Heran Darwin	19603/4292 (CRF D-3099-03	3247

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EXAMINER	
ODELL, LINDSAY T	

ART UNIT	PAPER NUMBER
1652	

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DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,555	DARWIN ET AL.	
	Examiner	Art Unit	
	Lindsay Odell	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-102* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-102 are pending.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 7-11, 64 and 69-76 drawn to methods of treating a pathogen infection comprising inhibiting proteasomal activity wherein the proteasomal activity is an AAA ATPase activity, classified in class 435, subclass 183.

II. Claims 2-6, 65*-68 and 74-76 drawn to methods of treating a pathogen infection comprising inhibiting proteasomal activity wherein the proteasomal activity is an proteasomal protease activity, classified in class 435, subclass 212.

III. Claims 21-24, 26-33 and 77-80 drawn to methods of treating a pathogen infection comprising inhibiting enzyme activity wherein the enzyme is a DNA repair enzyme, classified in class 435, subclass 183.

IV. Claims 21, 25-33, 77 and 81 drawn to methods of treating a pathogen infection comprising inhibiting enzyme activity wherein the enzyme is a flavin-like co-factor synthesis enzyme, classified in class 435, subclass 183.

V. Claims 38-43, drawn to methods of screening proteasomal inhibitor compounds comprising growing bacteria wherein the proteasomal inhibitor compound inhibits AAA ATPase activity, classified in class 435, subclass 29.

VI. Claims 44-48, drawn to methods of screening proteasomal inhibitor compounds comprising growing bacteria wherein the proteasomal inhibitor compound inhibits protease activity, classified in class 435, subclass 29.

VII. Claims 50-57, drawn to methods of screening DNA repair enzyme inhibitor compounds comprising growing bacteria, classified in class 435, subclass 29.

VIII. Claims 58-62, drawn to methods of screening flavin-like co-factor synthesis enzyme inhibitor compounds comprising growing bacteria, classified in class 435, subclass 29.

IX. Claims 89-94, drawn to methods of screening AAA ATPase activity inhibitor test compounds comprising using isolated protein having proteasomal protease activity, classified in class 435, subclass 7.71.

X. Claims 95-100, drawn to methods of screening protease inhibitor test compounds comprising using isolated protein having proteasomal activity, classified in class 435, subclass 7.71.

*Examiner notes that claim 65 is read to depend from claim 63 (not 64). As written, claim 65 depends upon claim 64; however, Examiner interprets this as an error because it does not make sense.

3. Claims 1 and 12-20 link(s) invention I to invention II. Claims 63 and 77-87 also link invention I to invention II. The restriction requirement between the linked inventions I and II is subject to the nonallowance of the linking claim(s) 1, 12-20, 63 and 77-87.

Claims 63-67 and 82-87 link invention III to invention IV. The restriction requirement between the linked inventions III and IV is subject to the nonallowance of the linking claim(s) 63-67 and 82-87.

Claims 34-37 and 49 link(s) inventions V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 34-37 and 49.

Claims 88 and 101-102 link(s) inventions IX and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 88 and 101-102.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are related because they are all drawn to methods of treating a pathogen infection by inhibiting an activity. Although the Groups are related, they are distinct inventions

because their methods have different products: the targets for activity inhibition are distinct. For example, the target for activity inhibition if Group I is AAA ATPase activity, that of Group II is proteasomal protease activity, that of Group III is a DNA repair enzyme activity and that of Group IV is a flavin-like co-factor synthesis enzyme activity. Thus, the Groups are patentably distinct, each from the other. In addition, the search required for each Group is not required for the other Group. For example, to search Group I requires a search of AAA ATPase activity, which is not required to search Groups II-IV. Likewise, to search Group II requires a search of proteasomal protease activity, which is not required to search Groups I and III-IV. Because these inventions are distinct for the reasons given above and the search required for each of Groups I-IV is not required for the other Groups, restriction for examination purposes as indicated is proper. Groups I-IV are patentably distinct, each from the other, and present a search burden on the Office if they were to be searched together.

Groups I-IV are related to Groups V-X because the methods of Groups I-IV can be used to inhibit the activities for which inhibitors are screened in the methods of Groups V-X. Although the Groups are related, they are distinct inventions because their methods have distinct method steps, substrates and products. For example, Groups V-X involve a method step of determining the effect of a known or suspected inhibitor, which is absent from the methods of Groups I-IV. In addition, the product of the method steps of Groups I-IV is inhibition of an activity in a pathogen *in vivo*, whereas the products of the method steps of Groups V-X are either an uninhibited or inhibited activity *in vitro*. Thus, Groups I-IV are patentably distinct from Groups V-X. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for

examination purposes as indicated is proper. Groups I-IV and V-X are patentably distinct, and it would present a search burden on the Office if they were to be searched together.

Groups V-VIII are related because they are all drawn to methods of screening inhibitor compounds using bacteria. Although the Groups are related, they are distinct inventions because their methods have different substrates and products. For example, the substrates of the method steps of Group V are known or suspected inhibitors of AAA ATPase activity, whereas the substrates of the method steps of Group VI are known or suspected inhibitors of proteasomal protease inhibitors. Thus, Groups V-VIII are patentably distinct, each from the other. In addition, the search required for each of the Groups is not required for the other Groups. For example, to search Group V requires a search of AAA ATPase activity inhibitors, which is not required for Groups VI-VIII. Likewise, to search Group VI requires a search of proteasomal protease inhibitors, which is not required for Groups V and VII-VIII. Because these inventions are distinct for the reasons given above and the search required for each of Groups V-VIII is not required for the other Groups, restriction for examination purposes as indicated is proper. Groups V-VIII are patentably distinct, each from the other, and present a search burden on the Office if they were to be searched together.

Groups V-VIII are related to Groups IX-X because they are both drawn to methods of screening inhibitor compounds. Although the Groups are related, they are distinct inventions because they have different method steps, substrates and products. For example, substrates of the methods of Groups V-VIII include bacteria, whereas the substrates of Group IX-X do not include bacteria, but include isolated protein having a particular activity. In addition, the products of the methods of Groups V-VIII are dead or live bacteria, whereas the products of the

method steps of Groups IX-X is inhibited or non-inhibited protein activity. Thus, Groups V-VIII and IX-X are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Groups V-VIII and IX-X are patentably distinct and present a search burden on the Office if they were to be searched together.

Group IX and Group X are related because they are both drawn to methods of screening inhibitor compounds using isolated protein. Although the Groups are related, they are distinct inventions because their methods have different substrates and products. For example, the substrates of the method steps of Group IX are known or suspected inhibitors of AAA ATPase activity, whereas the substrates of the method steps of Group X are known or suspected inhibitors of proteasomal protease inhibitors. Thus, Groups IX and X are patentably distinct. In addition, the search required for Group IX is not required for Group X. For example, to search Group IX requires a search of AAA ATPase activity inhibitors, which is not required for Groups X. Because these inventions are distinct for the reasons given above and the search required for Groups IX is not required for Group X, restriction for examination purposes as indicated is proper. Groups IX and X are patentably distinct and present a search burden on the Office if they were to be searched together.

Requirement for an Election of Species

5. This application contains claims directed to the following four patentably distinct species of the claimed inventions I, V and IX: methods of treating a pathogen infection comprising

inhibiting proteasomal activity wherein the proteasomal activity is an AAA ATPase activity that is an AAA ATPase forming ring-shaped complex, a proteasome associated nucleotidase, a mycobacterial proteasome ATPase or a proteasome accessory factor.

This application contains claims directed to the following two patentably distinct species of the claimed inventions II and VI: methods of treating a pathogen infection comprising inhibiting proteasomal activity wherein the proteasomal activity is an proteasomal protease that is either protease PrcA or protease PrcB.

This application contains claims directed to the following three patentably distinct species of the claimed invention X: methods of screening protease inhibitor test compounds comprising using isolated protein having proteasomal activity wherein the protease is PrcA, PrcB or protease1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2 and 64 are generic for invention I, claims 2-3 and 64-65 are generic for invention II, claim 38 is generic for invention V, claims 44-45 are generic for invention VI, claim 89 is generic for invention IX, and claims 95-96 are generic for invention X.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.
April 4, 2005

KATHLEEN KERR, PH.D.
PRIMARY EXAMINER